K063526

JUN 29 2007

510(k) Summary

As Required by 21 section 807.92 (c)

1-Submitter Name: A-M SYSTEMS, INC
2-Address: 131 Business Park Loop
Carlsborg, WA 98324 USA
3-Phone: 360 683 8300
4-Fax: 360 683 3525
5-Contact Person: Arthur B Green III
6- Submission Correspondent: Jay Mansour of Mansour Consulting LLC
845 Aronson Lake Court. Roswell, GA 30075 USA
Tel 678 908 8180. Fax 678 623 3765
7-Date summary prepared: October 14th, 2006
8-Device Trade or Proprietary Name: A-M SYSTEMS VIROMAX Viral and Bacterial Filter
9-Device Common or usual name: Breathing Filter
10-Device Classification Name: Breathing Circuit Bacterial Filter
11-Substantial Equivalency is claimed against K961914

12-Description of the Device:

The A-M SYSTEMS VIROMAX Viral and Bacterial Filter is a non-sterile, single patient use breathing filter consisting of a gas permeable filter membrane enclosed in a transparent plastic housing. When the A-M SYSTEMS VIROMAX Viral and Bacterial Filter is inserted into a breathing circuit, the respiratory gas passes through the electrostatically-charged hydrophobic filter membrane, thus trapping bacteria and viruses.

13-Intended use of the device: (refer to FDA forms attached)

This device is intended for use on all patient populations, in conjunction with other respiratory devices containing standard 15mm and/or 22mm fittings (such as breathing circuits) to filter respiratory gases where infection from airborne bacteria and viruses is a concern.

14-Safety and Effectiveness of the device:

This device is safe and effective as the other predicate device cited above.
This is better expressed in the tabulated comparison (Paragraph 14 below)

15-Summary comparing technological characteristics with other predicate device:

Please find below a tabulated comparison supporting that this device is substantially equivalent to other medical devices in commercial distribution. Also, Equivalency overview chart path is attached. **Refer to the explanations within the main submission.**

FDA file reference number	510k # K961914
Attachments inside notification submission file	510k FDA website print outs
TECHNOLOGICAL CHARACTERISTICS	**Comparison result**
Indications for use	Identical
Target population	
Design	Similar
Materials	
Performance	
Sterility	
Biocompatibility	Similar
Mechanical safety	Similar
Chemical safety	Not applicable
Anatomical sites	Identical
Human factors	
Energy used and/or delivered	Not applicable
Compatibility with environment and other devices	Similar
Where used	Identical
Standards met	Similar
Electrical safety	Not applicable
Thermal safety	
Radiation safety	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 2007

A-M Systems, Incorporated
C/O Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street NW
Buffalo, Minnesota 55313

Re: K063526
Trade/Device Name: A-M SYSTEMS VIROMAX Viral and Bacterial Filter
Regulation Number: 21 CFR 868.5260
Regulation Name: Breathing Circuit Bacterial Filer
Regulatory Class: II
Product Code: CAH
Dated: June 16, 2007
Received: June 19, 2007

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

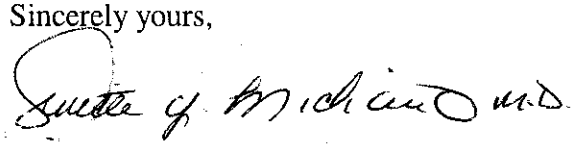
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063526

Device Name: A-M SYSTEMS VIROMAX Viral and Bacterial Filter

Indications For Use:

This device is indicated for use on all patient populations, in conjunction with other respiratory devices containing standard 15mm and/or 22mm fittings (such as breathing circuits) to filter respiratory gases where infection from airborne bacteria and viruses is a concern.

Prescription Use ✔ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K063526